

(4) Where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

(c) *Documentation.* (1) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated by the most responsible individual onsite at the processing facility or by a higher level official of the processor. These signatures shall signify that these records have been accepted by the firm.

(2) The records in paragraphs (a)(2) and (a)(3) of this section shall be signed and dated:

- (i) Upon initial acceptance;
- (ii) Upon any modification; and
- (iii) Upon verification and validation in accordance with §120.11.

(d) *Record retention.* (1) All records required by this part shall be retained at the processing facility or at the importer's place of business in the United States for, in the case of perishable or refrigerated juices, at least 1 year after the date that such products were prepared, and for, in the case of frozen, preserved, or shelf stable products, 2 years or the shelf life of the product, whichever is greater, after the date that the products were prepared.

(2) Offsite storage of processing records required by paragraphs (a)(1) and (a)(4) of this section is permitted after 6 months following the date that the monitoring occurred, if such records can be retrieved and provided onsite within 24 hours of request for official review. Electronic records are considered to be onsite if they are accessible from an onsite location and comply with paragraph (g) of this section.

(3) If the processing facility is closed for a prolonged period between seasonal packs, the records may be transferred to some other reasonably accessible location at the end of the seasonal pack but shall be immediately returned to the processing facility for official review upon request.

(e) *Official review.* All records required by this part shall be available for review and copying at reasonable times.

(f) *Public disclosure.* (1) All records required by this part are not available for public disclosure unless they have been previously disclosed to the public, as defined in §20.81 of this chapter, or unless they relate to a product or ingredient that has been abandoned and no longer represent a trade secret or confidential commercial or financial information as defined in §20.61 of this chapter.

(2) Records required to be maintained by this part are subject to disclosure to the extent that they are otherwise publicly available, or that disclosure could not reasonably be expected to cause a competitive hardship, such as generic type HACCP plans that reflect standard industry practices.

(g) *Records maintained on computers.* The maintenance of computerized records, in accordance with part 11 of this chapter, is acceptable.

§ 120.13 Training.

(a) Only an individual who has met the requirements of paragraph (b) of this section shall be responsible for the following functions:

(1) Developing the hazard analysis, including delineating control measures, as required by §120.7.

(2) Developing a Hazard Analysis and Critical Control Point (HACCP) plan that is appropriate for a specific processor, in order to meet the requirements of §120.8;

(3) Verifying and modifying the HACCP plan in accordance with the corrective action procedures specified in §120.10(b)(5) and the validation activities specified in §§120.11(b) and (c); and 120.7;

(4) Performing the record review required by §120.11(a)(1)(iv).

(b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed training in the application of HACCP principles to juice processing at least equivalent to that received under standardized curriculum recognized as adequate by the Food and Drug Administration, or shall be otherwise qualified through job experience to perform these functions. Job experience may qualify an individual to perform these functions if such experience

§ 120.14

21 CFR Ch. I (4–1–13 Edition)

has provided knowledge at least equivalent to that provided through the standardized curriculum. The trained individual need not be an employee of the processor.

§ 120.14 Application of requirements to imported products.

This section sets forth specific requirements for imported juice.

(a) *Importer requirements.* Every importer of juice shall either:

(1) Obtain the juice from a country that has an active memorandum of understanding (MOU) or similar agreement with the Food and Drug Administration, that covers the food and documents the equivalency or compliance of the inspection system of the foreign country with the U.S. system, accurately reflects the relationship between the signing parties, and is functioning and enforceable in its entirety; or

(2) Have and implement written procedures for ensuring that the juice that such importer receives for import into the United States was processed in accordance with the requirements of this part. The procedures shall provide, at a minimum:

(i) Product specifications that are designed to ensure that the juice is not adulterated under section 402 of the Federal Food, Drug, and Cosmetic Act because it may be injurious to health or because it may have been processed under insanitary conditions; and

(ii) Affirmative steps to ensure that the products being offered for entry were processed under controls that meet the requirements of this part. These steps may include any of the following:

(A) Obtaining from the foreign processor the Hazard Analysis and Critical Control Point (HACCP) plan and prerequisite program of the standard operating procedure records required by this part that relate to the specific lot of food being offered for import;

(B) Obtaining either a continuing or lot specific certificate from an appropriate foreign government inspection authority or competent third party certifying that the imported food has been processed in accordance with the requirements of this part;

(C) Regularly inspecting the foreign processor's facilities to ensure that the imported food is being processed in accordance with the requirements of this part;

(D) Maintaining on file a copy, in English, of the foreign processor's hazard analysis and HACCP plan, and a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part;

(E) Periodically testing the imported food, and maintaining on file a copy, in English, of a written guarantee from the foreign processor that the imported food is processed in accordance with the requirements of this part; or

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

(b) *Competent third party.* An importer may hire a competent third party to assist with or perform any or all of the verification activities specified in paragraph (a)(2) of this section, including writing the importer's verification procedures on the importer's behalf.

(c) *Records.* The importer shall maintain records, in English, that document the performance and results of the affirmative steps specified in paragraph (a)(2)(ii) of this section. These records shall be subject to the applicable provisions of § 120.12.

(d) *Determination of compliance.* The importer shall provide evidence that all juice offered for entry into the United States has been processed under conditions that comply with this part. If assurances do not exist that an imported juice has been processed under conditions that are equivalent to those required of domestic processors under this part, the product will appear to be adulterated and will be denied entry.

Subpart B—Pathogen Reduction

§ 120.20 General.

This subpart augments subpart A of this part by setting forth specific requirements for process controls.

§ 120.24 Process controls.

(a) In order to meet the requirements of subpart A of this part, processors of juice products shall include in their